UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MARIA ROBINSON,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION H- 20-3760
	§	
ETHICON INC. and JOHNSON & JOHNSON,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Pending before the court is a motion for partial summary judgment filed by defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (collectively, "Ethicon").[1] Dkt. 128. The court held a hearing on the motion for partial summary judgment on October 26, 2021. *See* Dkt. 157. Having considered the motion, response, reply, arguments made during the hearing, record evidence, and the applicable law, the court is of the opinion that the motion (Dkt. 128) should be GRANTED IN PART AND DENIED IN PART.

I. PROCEDURAL HISTORY

Robinson filed this lawsuit on March 23, 2013. Dkt. 1. Robinson's claims relate to the TVT-Obturator (TVT-O), a polypropylene mesh sling manufactured by the defendants that was implanted in Robinson's body on October 27, 2011, to treat stress urinary incontinence ("SUI"). Dkt. 1 (short-form complaint); Dkt. 63-1 (first amended master long form complaint); Dkt. 62 (transfer order); Dkt. 128 (motion for partial summary judgment (instant motion)); Dkt. 143 (plaintiff's response). Her claim was one of thousands of cases that were part of the Ethicon pelvic

[1] Ethicon, LLC, was a party at the time the instant motion was filed, but the parties have since filed a stipulation of dismissal as to Ethicon, LLC, only. Dkt. 153.

repair systems products multi-district litigation ("MDL") presided over by Judge Joseph Goodwin in the Southern District of West Virginia. *See In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-2327, MDL No. 2327 (S.D.W. Va.). Ethicon filed a motion for partial summary judgment on August 13, 2019, while the case was still pending in the MDL court, and the motion was fully briefed. *See* Dkts. 45, 46, 52, 54. When Judge Goodwin transferred the case to this court on October 20, 2020, the motion for partial summary judgment and several motions to strike experts were pending. Dkt. 62. Rather than ruling on potentially stale motions, the court denied all of the then-pending motions without prejudice to refiling. Dkt. 84.

The parties filed a joint discovery case management plan in this court on November 24, 2020, and the court entered a scheduling order on February 22, 2021. Dkts. 106, 110. Pursuant to the scheduling order, Robinson filed supplemental expert reports in May 2021. *See* Dkt. 125. Ethicon moved to strike portions of those supplemental reports that addressed some of the issues that Ethicon had raised in the motion for partial summary judgment in the MDL court, arguing that they were not proper supplemental opinions and instead relied on information that was available at the time the original expert reports were filed. *Id.* On September 2, 2021, the court granted Ethicon's motion to strike certain opinions expressed in the supplemental expert reports. Dkt. 151.

In July and August of 2021, the parties re-filed the motions to strike expert testimony that were not ruled on by the MDL court, and on August 6, 2021, Ethicon filed a renewed motion for partial summary judgment. Dkts. 126, 128–32. This memorandum opinion and order relates to the renewed motion for partial summary judgment (Dkt. 128). Because the court has stricken the objected-to portions of the supplemental expert reports, the court will not rely on the stricken opinions when ruling on this motion. Robinson filed a response to the motion for partial summary judgment, and Ethicon filed a reply. Dkts. 143, 144. The court held a hearing on October 26,

2021, during which the parties addressed some of the issues raised in the motion for partial summary judgment and response. *See* Dkts. 155 (order setting hearing); 157. The motion for partial summary judgment (Dkt. 128) is now ripe for disposition.

II. LEGAL STANDARD

A court shall grant summary judgment when a "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[A] fact is genuinely in dispute only if a reasonable jury could return a verdict for the nonmoving party." *Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548 (1986). If the moving party meets its burden, the burden shifts to the non-moving party to set forth specific facts showing a genuine issue for trial. Fed. R. Civ. P. 56(e). The court must view the evidence in the light most favorable to the non-movant and draw all justifiable inferences in favor of the non-movant. *Env't Conservation Org. v. City of Dallas*, 529 F.3d 519, 524 (5th Cir. 2008).

III. WITHDRAWN CLAIMS

Ethicon notes in its motion that Robinson had stated that she was withdrawing certain claims in her response to the motion for partial summary judgment filed in the MDL court. Dkt. 128. Robinson confirmed in her response to the instant motion that she is indeed withdrawing her claims for strict liability manufacturing defect (Count II), common law fraud (Count VI), fraudulent concealment as a separate cause of action (Count VII), constructive fraud (Count VIII), negligent infliction of emotional distress (Count X), breach of warranty (Counts XI and XII), violations of the Texas Deceptive Trade Practices Act (Count XIII), and unjust enrichment (Count XV). Dkt. 143. She additionally advised that she is withdrawing her claims for negligence-

manufacturing defect and defective product (Count IV). *Id.* These claims are therefore DISMISSED. Because the plaintiff is voluntarily withdrawing these claims, Ethicon's motion for partial summary judgment on these claims (Dkt. 128) is DENIED AS MOOT.

IV. FACTS AND ANALYSIS

This is primarily a products liability case, and in the remainder of this order, the court must determine whether to grant partial summary judgment in Ethicon's favor on Robinson's design defect claims, her negligence misrepresentation claim, and her other negligence-based claims. Robinson's expert Dr. Niall Galloway concluded that Robinson suffered multiple mesh-related complications from her TVT-O implant in October 2011. Dkt. 143 & Ex. A. She has since undergone three surgical revision and removal procedures. Dkt. 143 & Exs. A, S. She contends that Ethicon should have warned her about the risks associated with the TVT-O, that the TVT-O was not reasonably safe for its intended use and was defective with respect to its design, and that there were safer alternative designs to treat SUI, including the following:

(1) a native tissue or autologous fascial sling;

(2) an allograft sling;

(3) the Burch procedure;

(4) paravaginal repair, which also uses native tissue;

(5) a retropubic sling;

(6) modified Prolene mesh with larger pores; and

(7) a polymer-based mid-urethral sling comprised of PVDF.

Dkts. 63-1, 143.

Ethicon contends that these are not "safer alternative designs" under Texas law. *See* Dkt. 144 (arguing that alternative procedures or surgeries, completely different products, and

products not approved by the federal Food and Drug Administration ("FDA") do not qualify as alternative designs under Texas law). Ethicon additionally asserts that (1) Robinson's negligent misrepresentation claim is duplicative of Robinson's failure-to-warn claim; (2) it is precluded by the learned intermediary doctrine because a physician implanted the device; and (3) the other negligence-based claims are duplicative of the other failed claims. Dkt. 128. Ethicon thus urges the court to grant summary judgment in its favor on Robinson's design defect, negligent misrepresentation, and other negligence-based claims. Dkts. 128, 144.

Robinson argues that because there were safer alternative designs, because Ethicon's warning to her physician about the risks associated with the TVT-O device was inadequate, and because the negligence claims are based on the valid design-defect claims, the court should not grant summary judgment on any of these claims. Dkt. 143.

The court will first consider the design defect claim, and then determine whether the negligent misrepresentation claim should be dismissed because it is barred by the learned intermediary doctrine and whether the other negligence claims should be dismissed as duplicative of dismissed claims.

A. Design Defect Claim

Under Texas law, a design defect claim requires a plaintiff to prove "that (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex.2009). Here, the parties dispute the second element—whether there is sufficient evidence that a safer alternative design existed.

While a plaintiff attempting to prove a design defect must prove that a safer alternative design existed, this requirement is not meant to eliminate entire categories of useful products from

the market. *Caterpillar Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995). Thus, a "'substantially different product' cannot constitute a safer alternative design." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 766 (5th Cir. 2018) (quoting *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 770 (Tex. App.—Houston [14th] Dist. 2009, no pet.), and citing *Caterpillar*, 911 S.W.2d at 385); *see Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-2256, 2020 WL 6365545, at *4 (S.D. Tex. Aug. 31, 2020) (Gilmore, J.) ("To prove a safer alternative design exists, a plaintiff must prove that the alternative design would have reasonably prevented or significantly reduced the risk of the claimant's injury without substantially impairing the product's utility."). A safer alternative design must (1) have prevented or significantly reduced the risk of the plaintiff's injury "'without substantially impairing the product's utility'"; and (2) have been both "'economically and technologically feasible'" at the time the allegedly defectively designed product was manufactured or sold. *Casey v. Toyota Motor Eng'g & Mfg. N. Am, Inc.*, 770 F.3d 322, 331 (5th Cir. 2014) (quoting Tex. Civ. Prac. & Rem. Code Ann. § 82.005(b)). "This design need not be actually built and tested; a plaintiff must show only that the alternative design was 'capable of being developed.'" *Genie Indus. Inc. v. Matak*, 462 S.W.3d 1, 7 (Tex. 2015). "A design is not a safer alternative if, under other circumstances, [it would] impose an equal or greater risk of harm than the design at issue." *Casey*, 770 F.3d at 331.

1. Safer Alternative Design Requirement for Medical Devices

Robinson first argues that the safer alternative design requirement, which is a requirement for design defect claims under the Texas products liability statute as well as common law, does not apply to medical devices. *See* Dkt. 143 (referring to Tex. Civ. Prac. & Rem. Code Ann. § 82.005). Indeed, the Texas products liability statute states that it does not apply to "drugs" or "devices" as those terms are defined in the federal Food, Drug, and Cosmetic Act, and this case is

about such a device. *See* Tex. Civ. Prac. & Rem. Code Ann. § 82.005(d)(2) (indicating that the section does not apply to these products). However, the statute also states that it does not supersede common law, and Texas courts considering common law products liability claims about drugs and devices require a showing of a safer alternative design, notwithstanding the statutory exclusion. *Id.* § 82.005(e) (stating that the section "is not declarative, by implication or otherwise, of the common law with respect to any product"); *Labiche v. Johnson & Johnson*, No. H-20-4249, 2021 WL 3719554, at *1 & n.5 (S.D. Tex. Aug. 19, 2021) (Hughes, J.) (collecting cases) ("Courts who have applied the elements for design defects to medical devices under Texas law – after this section was enacted – have consistently required a safer alternative design to be shown."). Robinson's design defect claim is a common law claim; she therefore must show there was a safer alternative design. *See* Dkt. 68-1 (long-form complaint asserting a design defect claim without citing the Texas products liability statute).

2. Alternative Procedures (Proposed Alternative Designs 1, 2, 3, and 4)

Ethicon argues that the autologous fascia sling (alternative design ("A.D.") 1), the allograft sling (A.D. 2), the Burch procedure (A.D. 3), and paravaginal repair (A.D. 4) are all alternative procedures and are not alternative designs. Dkt. 128. It primarily presents caselaw to support this argument, though it also cites to Robinson's expert reports and deposition testimony. *See id.*; *see also* Dkt. 156, Ex. 1 (complete transcript of Dr. Peter Lotze testimony).

Robinson discusses the advantages of the Burch procedure in the background section of her response, but she does not address why this procedure should be considered a safer alternative design in the argument portion of her brief. *See* Dkt. 143. She does, however, argue that autologous and allograft slings serve the same function as TVT-O and were both economically

and technologically feasible at the time of Robinson's TVT-O implant. *Id.* She does not address paravaginal repair except to say the procedure uses native tissue. *See id.*

Two judges in this district—Judge Hughes and Judge Gilmore—have recently ruled in cases very similar to the instant case that different surgical procedures are not alternative designs. Judge Hughes ruled that (1) the Burch procedure was a different procedure than use of pelvic mesh, (2) an organic sling was a different product than a synthetic sling, and (3) thus neither qualified as a safer alternative design. *See Labiche*, 2021 WL 3719554, at *2 ("Even though the Burch procedure and TVT-S pelvic mesh may aim for the same result – treating urinary incontinence – they are not alternative designs. Because the Burch procedure is an alternative procedure that requires an abdominal incision and is more invasive, it cannot be a safer alternative design.") ("The use of organic sling material is not a change in the design of the TVT-S pelvic mesh but a different product."). Judge Gilmore agreed that alternative procedures do not qualify as safer alternative designs. *Pizzitola*, 2020 WL 6365545, at *4 ("[T]o the extent that Plaintiff's claim is based on alternative surgical procedures or non-surgical exercises as a safer alternative design to the Prolift mesh and TVT-O sling, that aspect of Plaintiff's design defect claim must fail."). However, she determined that the defendants had not shown there was an absence of material fact with regard to devices that use human or animal tissue instead of synthetic mesh, noting that under Texas law "[p]roducts are not substantially different simply because they are comprised of different materials." *Id.* at *5.

The court agrees that under Texas law a product is not precluded from being a safer alternative design simply because it is made of a different material. Here, however, Ethicon met its initial summary judgment burden by asserting that Robinson had no evidence that a safer alternative design exists, arguing that the Burch procedure and the use of organic slings are not

alternative designs but alternative procedures, and presenting evidence supporting these argument.[2] *See Transamerica Ins. Co. v. Avenell* , 66 F.3d 715, 718–19 (5th Cir. 1995) ("For any matter on which the non-movant would bear the burden of proof at trial . . . , the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial."); *see also Celotex*, 477 U.S. at 323–25 ("Once a movant who does not have the burden of proof at trial makes a properly supported motion, the burden shifts to the nonmovant to show that a summary judgment should not be granted."). Robinson presents some evidence supporting her view that at least some of these products would have significantly reduced the risk of her injury and that they were economically and technologically feasible at the time of Robinson's procedure; the issue presented by Ethicon's motion, however, is whether they are entirely different products/procedures than the TVT-O. *See* Dkt. 143, Ex. D at 28 (Margolis Expert Rep.) (opining that the Burch procedure is a feasible and safer alternative to TVT that "eliminates the severe, chronic and debilitating mesh related complications" and that autologous fascia slings and allograft slings are also safer). As the Fifth Circuit noted in *In re DePuy Orthopaedics*, this is a "thorny question of identity and definition . . . practically impossible to settle in the abstract." 888 F.3d at 766. The Fifth Circuit's straightforward example of a different design that is actually a different product is that adding two more wheels to a motorcycle creates a safer but substantially different product. *See id.* The court in *DePuy* decided that the proposed alternative design it was considering—use of metal-on-plastic hip implants as opposed to metal-on-metal hip implants—

[2] Ethicon provides testimony that the autologous sling is a "much more morbid procedure" that often "led to slightly more voiding dysfunction" and that native tissue repair was "more invasive." Dkt. 128, Ex. B at 30–31 (Kent Dep.).

was viable. *Id.* It noted a distinction in design defect cases finding a difference in the "*kinds* of functions for which the alleged defective [product] was designed" and a "slight difference in *degree*—that is, that the alternative does all the things for which the allegedly defective product was designed, but does not do one of them quite as well." *Id.* at 767. The former would not constitute viable alternative designs, but the latter may. *See id.*

Here, the evidence provided by Robinson is insufficient for a reasonable juror to conclude that use of organic materials is essentially the same kind of product and procedure as use of synthetic mesh and that the distinction between the two is, instead, one of degree. *Cf. Meindertsma v. Ethicon*, No. 1:20-CV-00708-RP, 2021 WL 2010355, at *3 (W.D. Tex. May 17, 2021) (finding that autologous fascia lata POP repair is a substantially different product than Prolift, a polypropylene mesh product designed by Ethicon, and is actually a procedure, not a design); *Castillo v. Bos. Sci. Corp.*, No. 7:20-CV-123, 2020 WL 5608510, at *5 (S.D. Tex. Sep. 18, 2020) (Alvarez, J.) ("Plaintiff's complaint mentions an FDA communication and White Paper that reference 'traditional non-mesh repair,' but even if the Court were to accept this as a safer alternative to the Product, this amounts to a substantially different product because it does not contain mesh."); *Cofresi v. Medtronic, Inc.*, 450 F. Supp. 3d 759, 766 (W.D. Tex. 2020) (finding that using biomesh for a hernia repair instead of Prolene mesh is an entirely different product not a safer alternative design).

The court finds that Robinson has not met her burden of showing that there is an issue of material fact that the Burch procedure, an allograft sling, an autologous fascia sling, and paravaginal repair are safer alternative designs as opposed to entirely different procedures or products. Accordingly, Ethicon's motion for partial summary judgment relating to these products (A.D. 1–A.D. 4) is GRANTED.

2. Retropubic Sling (Alternative Design 5)

In her response to Ethicon's motion or partial summary judgment, Robinson asserts that a retropubic sling is a safer alternative design. Dkt 143. She argues that it is safer because a retropubic sling does not require placement in the dynamic muscles of the groin or require passage through the obturator internus muscles near the obturator nerve. *Id.* (citing Ex. S, which is the deposition testimony of Dr. Lotze). She notes that retropubic slings were available on the market at the time of Robinson's implant, relying on the testimony of the surgeon who removed the TVT-O from Robinson. *Id.* & Ex. S at 8 (noting he performed three different surgeries to remove the TVT-O).

In reply, Ethicon asserts that this argument in the response to the instant motion is the first time Robinson has ever stated that a retropubic sling is a safer alternative design. Dkt. 144. Ethicon contends that Robinson does not have any evidence that this alternative design would have prevented her injuries. *Id.* Ethicon argues that the court cannot make a logical leap from testimony that the TVT-O is defectively designed to other designs having been a better choice for Robinson without expert testimony. *Id.*

Robinson relies on the deposition testimony of the surgeon who performed the surgeries on her to remove the TVT-O, Dr. Peter Lotze. Lotze testified that he primarily used retropubic slings to treat SUI in the time period that Robinson had her original surgery. Dkt. 143, Ex. S at 93. He testified that one of the advantages of retropubic slings is that "they really don't get into dynamic muscle groups and that gives them an advantage that—over what you would see with a transobturator sling." Dkt. 143, Ex. S at 116. While certainly it is intuitive that if the retropubic sling does not impact the same muscle groups then it may not cause the same problems, but he

does not discuss whether it creates a whole different set of problems or would have even worked in Robinson's case. Ethicon is correct that neither the court nor the jury can make the logical leaps needed to go from this snippet of testimony to the conclusion that a retropubic sling was a safer alternative design, even viewing the testimony in the light most favorable to Robinson. Additionally, the initial briefing suggests that the retropubic sling is a different procedure since it impacts different muscle groups,[3] and Lotze's deposition testimony supports a conclusion that it is an entirely different procedure.[4]

Robinson has not met her burden of demonstrating that there is an issue of material fact that the retropubic sling is a safer alternative design. Accordingly, Ethicon's motion for partial summary judgment on A.D. 6 is GRANTED.

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[3] Robinson invites the court to follow the MDL Court and the Fourth Circuit in finding that the retropubic sling is an acceptable safer alternative design to the transobturator sling like the TVT-O. Dkt. 138. The case she refers to is *Campbell v. Bos. Sci. Corp.*, 882 F.3d 70, 79 (4th Cir. 2018). In *Campbell*, the Fourth Circuit held that the jury had received evidence regarding a "safer alternative design" because, "[f]or example, one expert discussed a comparative study of the Obtryx and another [Boston Scientific Corporation] device that found no difference in cure rates between the two devices but more groin pain among women who received the Obtryx." 882 F.3d at 79. The court does not mention a retropubic sling, and, if the devices it is discussing are retropubic slings, it is clear an expert was discussing it. Additionally, it was disputed whether under West Virginia law, at the time, the plaintiff even had to prove a safer alternative design as a separate element. *See id.* at 80. We do not have the same expert testimony here, and this case is being considered under Texas law. So, *Campbell* is not helpful.

[4] "Q: Are there advantages to using an inside-out obturator approach like the TVT-O as opposed to using a retropubic approach or an outside-in?
A: I don't think a inside-out versus and outside-in in terms of how you're going to go about doing the sling is necessarily advantageous. I would argue that the outside-in approach would allow a person to better hug the static portion of the muscles that the mesh is eventually going to be placed in. I think you lose some of that control with an inside-out approach. Theoretically, the transobturator sling should avoid major vascular bundles such as the external iliac, the femoral nerve, the bladder, and the organs. Despite that, there are case reports of injury to each of those things with a transobturator sling, albeit that risk is profoundly rare and certainly less than what you would see with a retropubic sling." Dk. 156, Ex. 1 at 18–19.

3. Modified Prolene Mesh with Larger Pores (Alternative Design 6)

Robinson contends that the TVT device is a small pore mesh and causes more complications than lighter, larger pore meshes. Dkt. 143 (citing Ex. H). She presents evidence that an increased pore size in combination with a reduction in the amount of material used may "have improved the safety of the TVT and reduced the tissue reaction." *Id.* (citing Ex. G (Kling Dep.) at 363 (stating that if you increase the pore sizes "you will reduce the materials and you will improve the tissue reaction"). She asserts that Ethicon submitted an application to the FDA for premarket approval (under § 510(k), 21 U.S.C. § 360(k)) for a TVT device using pore sizes 600% larger and with less weight, but it did not bring this mesh with larger pores to the market. *Id.* (citing Ex. I). She also asserts that Ethicon obtained a patent in Germany for a mesh with a larger pore size in 2002. *Id.* (citing Ex. J, which discusses a mesh made of PVDF). She notes that courts applying Texas law have held that modified Prolene mesh with larger pores is a safer alternative. *Id.* (citing *Fox v. Ethicon, Inc.*, No. 2:12-cv-0878, 2016 WL 3748509, at *11 (S.D. W. Va. July 8, 2016); *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 U.S. Dist. LEXIS 15352, at *2555 (S.D. W. Va. Feb. 3, 2014)). In *Fox*, the court found that the plaintiff had shown there was a question of material fact that PVDF, laser cut edges, and larger pore/lighter weight mesh were safer alternative designs. 2016 WL 3748509, at *11. In *Lewis*, the court held that the plaintiff had to provide evidence of a safer alternative design and that she had done so. 2014 U.S. Dist. LEXIS 15352.

Ethicon asserts that using a lighter weight, larger pore mesh is not a safer alternative design under Texas law. Dkt. 144. It relies primarily on a recent opinion by Judge Hughes in which Judge Hughes opines that this type of product is not a safer alternative design because it is not approved by the FDA for use in a mid-urethral sling to treat SUI. *Id.* (citing *Labiche*, 2021 WL 3719554, at *2). Ethicon also points out that Robinson does not have any expert testimony

indicating that if this or her other alternative types of synthetic mesh were used that it would have prevented her injuries. *Id.*

During the hearing, Ethicon's counsel pointed out that the experts upon which Robinson relies for this theory are *general* experts, not *case-specific* experts, and that they therefore cannot testify that mesh with larger pores would have been safer in Robinson's case, specifically. Robinson's counsel agreed that there is no case specific expert who has provided an admissible report that opines that a mesh with larger pores would have prevented or decreased Robinson's specific injuries. The testimony she cited in her response was from a general expert who was not specifically discussing Robinson's injuries.[5] Thus, Robinson has presented no evidence that would be admissible at trial to show that a mesh with larger pores was a solution in her case.

The fact that it was not approved by the FDA is also a problem. Judge Hughes concisely opined in *Labiche* that a design with larger pores is not feasible because the FDA had not yet approved it. The court agrees with Judge Hughes with the caveat that FDA approval alone is not necessarily dispositive under Texas law because the alternative design need only be *capable of being developed*. If Robinson could show this alternative were capable of being developed by having an expert opine that if Ethicon had followed through with an application for approval the FDA likely would have approved this design, there is a possibility that even though the FDA had

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[5] One of Robinson's general experts opined that 'the Prolene mesh used in Ethicon's TVT products, including the TVTO, is not suitable for implantation in the vagina. Despite developing newer, safer polypropylene meshes that had larger pores and were lighter weight, Ethicon continued to use the old construction Prolene mesh which is associated with a number of problems discussed in this report."[5] Dkt. 143, Ex. D (Margolis Report). The expert further opined, "[i]f mesh has to be used for the treatment of SUI in a patient, a lighter weight, larger pore mesh, less stiff mesh with sealed edges would be safer for patients and was feasible because Ethicon was using a much lighter weight mesh in other pelvic products and in hernia products for many years." *Id.* There is, however, no expert to testify that it was feasible, specifically, in Robinson's case.

not approved the device at the time, the testimony or report would be sufficient to support a question of material fact to support the safer alternative design element. However, as Ethicon pointed out during the hearing, Robinson did not designate a regulatory expert who could testify about the FDA's approval process or how such an application would have been viewed. Robinson's counsel agreed that there was no regulatory expert to offer such testimony but urged the court to allow the jury to look at the evidence and make the determination. That, however, is not how it works when a motion for partial summary judgment is filed. Since Ethicon met its initial burden, Robinson must show that there is a question of material fact for the jury to consider. Robinson has not and cannot without the proper experts show there is an issue of material fact that (1) this would have been a safer design for Robinson's situation; and (2) it was capable of being developed. Accordingly, Ethicon's motion for partial summary judgment on A.D. 6 is GRANTED.

4. Polymer-Based Mid-Urethral Sling Comprised of PVDF (Design 7)

The final safer alternative design Robinson proposes is a polymer-based mid-urethral sling comprised of PVDF. Dkt. 143. The arguments relating to PVDF are similar to the arguments made about modified Prolene mesh with larger pores. Ethicon argues that the PVDF mid-urethral sling was not available and was not an economically feasible alternative to a TVT-O sling when Robinson had her surgery. Dkt. 128. Ethicon asserts that PVDF mesh has not even been cleared by the FDA for use in the United States. *Id.* It also presents evidence that PVDF is more expensive and difficult to handle than the TVT-O and thus, in Ethicon's view, not a better alternative. *Id.* (citing Ex. E (Klinge Dep.) at 517 (testifying that PVDF is "definitely more expensive" than polypropylene and "more difficult to handle" but stating he did not know how much more expensive)).

Robinson argues that in 2011 PVDF was a safer, practical, and feasible alternative to the implant Robinson received. Dkt. 143. She points out that Ethicon has been aware that PVDF is more resistant to degradation than Prolene mesh since at least 1990, it received clearance from the FDA under section 510(k) of the Food, Drug and Cosmetic Act for a suture containing PVDF named "Pronova" in 2000, it obtained a German patent for a PVDF mesh implant with a larger pore size in 2002, and there was already a PVDF sling called DynaMesh used in Europe to treat incontinence when Robinson had her original surgery, so there was no economic or engineering barrier to using PVDF. *Id.* Moreover, while Robinson acknowledges that the FDA has not specifically approved the use of PVDF for a device to treat SUI, she notes that a mesh containing PVDF has been cleared by the FDA for hernia repair since 2008, with a mesh product comprised fully of PVDF was approved in 2013 for use in hernia repairs. *Id.* Robinson asserts that, moreover, the FDA does not regulate the practice of medicine, and physicians routinely use products "off-label." *Id.* (citing *Leigh v. Danek*, 28 F. Supp. 2d 401, 404 (N.D. Tex. 1998)). Robinson additionally argues that Texas law does not require testing to prove a safer alternative design, and that she only need show the product is capable of being developed. *Id.* (citing *Gamboa v. Centrifugal Casting Co.*, No. H-14-1273, 2015 WL 6835359 (S.D. Tex. Nov. 6, 2015) (Miller, J.) (noting that "Texas law does not require testing to prove that a safer alternative design existed"), *Castillo v. Bos. Sci.*, No. 1:20-CV-513-RP, 2020 U.S. Dist. LEXIS 93020, at *12 (W.D. Tex. May 28, 2020) ("A proposed alternative 'design need only prove "capable" of being developed.'" (quoting *Gen. Motors Corp. v. Sanchez*, 997 S.W.2d 584, 592 (Tex. 1999)), and *Genie Indus.*, 462 S.W.3d at 7).

Ethicon argues in reply that while PVDF may have been used in other countries or for other physical conditions, it is not approved by the FDA for a mid-urethral sling to treat SUI and is thus

not a safer alternative treatment. Dkt. 144. It asserts that a hypothetical product design that is not even available cannot be considered a safer alternative design. *Id.* Moreover, as with the proposed Prolene mesh with larger pores alternative design, Ethicon's counsel pointed out during the hearing that Robinson has no expert to testify that PVDF mesh was a safer alternative design with regard to Robinson's specific procedure.

Robinson relies on *Leigh v. Danek* for her argument that doctors can use a medical device off label because the FDA does not regulate physicians. *See* Dkt. 143. *Leigh* is about an alleged conspiracy to get physicians to insert a device into patients' pedicles even though the device had not been approved by the FDA to be marketed or sold for that purpose. 28 F. Supp. 2d at 404. The Leigh physician knew the screws were not approved for the purpose he used them and used his medical judgment to determine it was the correct treatment for the patient with full knowledge that it was not approved by the FDA. *Id.* The court noted that the FDA regulates how manufacturers label medical devices, it does not regulate the practice of medicine, and doctors routinely use products off label. *Id.* Here, Robinson offers no regulatory expert to testify about the impact of FDA approval or lack thereof with regard to the types of devices at issue. Thus, while the court agrees with Robinson in general that physicians often use their medical training and expertise to prescribe a drug or possibly use a product in a way that the FDA has not approved, it is unclear practically how that impacts the proposed alternative designs in this case and Ethicon's obligations under FDA regulations.

Some discussion of the Texas cases that established the capable-of-being-developed standard is helpful in determining how that standard should be applied in this case. In *Genie Industries v. Matak*, the Texas Supreme Court noted that the alternative design "need not be actually built and tested; a plaintiff must show only that the alternative design was 'capable of

being developed.'" 462 S.W.3d at 7. That case was about aerial lifts used to raise a worker on a platform. *Id.* at 3. The machine included a warning not to move it while in use, but workers in this case moved the lift while there was a worker on it, it tipped over, and the worker who was on the lift died. *Id.* at 3, 6. A jury found the lift was defectively designed, and the Texas Supreme Court ultimately overturned the verdict, holding that the lift was not unreasonably dangerous as a matter of law. *Id.* at 6, 12. The court's decision turned on the fact that the danger a user will ignore the user manual, signs on the lift, and the danger that is obvious to even a casual observer, did not outweigh the utility of the product. *Id.* at 11–12. Thus, this case was not about a product that was possibly safer and just had not been developed. *See id.*

The *Genie Industries* court relied on *General Motors v. Sanchez* for its statement of the law that the design need only be capable of being developed. *See id.* at 7. In *Sanchez*, which was about an alleged design defect in a GM truck's transmission, the court noted that "the plaintiffs did not have to build and test an automobile transmission to prove a safer alternative design." 997 S.W.2d 584, 587, 592 (Tex. 1999). Basically, this aspect of the case indicates that the expert does not have to make a prototype. *Id.* at 592. The court ultimately held that the expert's conclusion regarding a safer alternative design raised a fact question for the jury. *Id.*

While the "capable of being developed" language in these cases posits the question of whether the non-FDA approved devices, and particularly one that was already being used in Europe, can be considered safer alternative designs under Texas law, these cases are different than the instant case because there was no regulatory agency in charge of transmissions or lifts that had an impact on the feasibility determination. One of the cases Robinson cites, however, is more on point. *Castillo v. Boston Scientific* is about a polypropylene mesh implant used to treat SUI called the Advantage Fit System. 2020 U.S. Dist. LEXIS 93020, at *2. It was also part of a Pelvic Repair

Systems MDL. *Id.* at *4. After remand from the MDL, the district court considered a motion for summary judgment on the design defect claim. *Id.* at *4, *7–*9. The court determined that the plaintiff had presented an issue of material fact whether a sling with less polypropylene such as Ultrapro was a safer alternative design. *Id.* at *11–*12. It noted that the proposed alternative design need only be capable of being developed, and the fact that the plaintiff could "point to an extant product as an example of the proposed alternative design strongly suggests that the design is indeed less harmful, as functional, and as feasible." *Id.* at *12. It found that expert testimony that the reasonable alternative design could have been practically adopted at the time of sale was sufficient to raise the issue of fact. *Id.* (citing *Sanchez*, 997 S.W.2d at 592). Here, however, as noted with regard to the larger-pored Prolene mesh, Robinson has not designated a regulatory expert who can testify that a similar product comprised of PVDF mesh instead of polypropylene mesh was capable of being developed in light of its status with the FDA.

There is no question that "'off-label' usage of medical devices . . . is an accepted necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine," and healthcare providers, thus, can "'prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.'" *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, 121 S. Ct. 1012 (2001) (quoting 21 U.S.C. § 396). However, without experts to testify about the regulatory framework and opine that Ethicon could have made and marketed a mid-urethral sling out of PVDF prior to FDA approval that physicians could have used off-label, Robinson does not have what she needs to provide an issue of material fact for trial. The evidence available is insufficient for a reasonable juror to determine that a PVDF mesh device was "capable of being developed" here in the United

States or that it would have been safer for Robinson, specifically. Ethicon's motion for summary judgment on A.D. 7 is therefore GRANTED.

B. Negligent Misrepresentation

Ethicon argues that the negligent misrepresentation claim should be dismissed under the learned intermediary doctrine, which it asserts applies here because an intermediary was in charge of passing along warnings to the intermediary's patient. Dkt. 128 (citing *Gonzalez v. Bayer Healthcare Pharms., Inc.*, 930 F. Supp. 2d 808, 814 (S.D. Tex. 2013)). Ethicon argues that Robinson cannot avoid the learned intermediary doctrine by simply repackaging her failure-to-warn claim as a negligent misrepresentation claim, and it seeks summary judgment on the negligent misrepresentation claim because it is "merely [a] repurposed failure to warn claim[] and because the learned intermediary doctrine applies." *Id.*

Under Texas law, a plaintiff asserting a negligent misrepresentation claim must prove:

> "(1) the representation is made by a defendant in the course of his business, or in a transaction in which he has a pecuniary interest; (2) the defendant supplies "false information" for the guidance of others in their business; (3) the defendant did not exercise reasonable care or competence in obtaining or communicating the information; and (4) the plaintiff suffers pecuniary loss by justifiably relying on the representation."

Matter of Life Partners Holdings, Inc., 926 F.3d 103, 123 (5th Cir. 2019) (quoting *Fed. Land Bank Ass'n of Tyler v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991)). In the long-form complaint, Robinson asserts that Ethicon negligently misrepresented the pelvic mesh's side effects and Robinson was injured as a result. Dkt. 63-1 (Claim IX). The "'gravamen' or 'crux' of [the negligent misrepresentation] claim . . . is that [Ethicon] furnished inadequate warnings to physicians and the public," and that the physicians and public relied on the misrepresentations. *Gutierrez v. Ethicon,*

Inc., No. 5:20-cv-00093-RCL, 2021 WL 2431016, at *18 (W.D. Tex. Apr. 23, 2021). Thus, the learned intermediary doctrine applies. *See id.*

Under the learned intermediary doctrine, a manufacturer only has a duty to warn the prescribing physician of the product's dangers. *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (citing *Bean v. Baxter Healthcare Corp*., 865 S.W.2d 656, 663 (Tex. App.—Houston [14th Dist.] 1998, no writ)). However, a manufacturer may still be held liable for injuries sustained by a patient if 1) the warning to the physician was defective; and 2) the failure to warn was a producing cause of the patient's condition or injury. *Porterfield*, 183 F.3d at 468 (citing *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 911 (Tex. App.—El Paso 1989, writ denied)). "While the learned intermediary doctrine shifts the manufacturer's duty to warn from end user to intermediary, the plaintiff's burden of proof remains the same, i.e., to prove the product's warning was inadequate." *Gonzalez*, 930 F. Supp. 2d 808, 813 (S.D. Tex. 2013) (Harmon, J.) (citing *Centocor, Inc. v. Hamilton*, 372 S.W. 3d 140, 166 (Tex. 2012)). Whether a warning is adequate is a question of fact to be determined by the jury. *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 592 (Tex. 1986).

Robinson provides testimony from the physician who implanted the TVT-O. *See* Dkt. 143, Ex. P at 8. The physician testified that Ethicon sales representatives visited him more than ten times to discuss the risks and benefits of TVT-O, that Ethicon proctors trained him how to implant it, and that he expected Ethicon to inform him about any severe complications with the TVT-O that were known. Dkt. 143, Ex. P at 99–100, 109, 111, 121 (Kent Dep.). He stated that he relied on the information provided by Ethicon to fully inform the patient, including information in the product's Instructions for Use, and he did not warn Robinson about anything that was not included in the Instructions for Use. *Id.* at 137–40, 147. The Instructions for Use did not warn about a risk

of chronic or long-term pain. *See id.* at 140–41; Dkt. 143, Ex. Q. The physician testified that if Ethicon had informed him that the TVT-O could cause permanent nerve damage and severe permanent pain, he would have told Robinson. Dkt. 143, Ex. P at 147-48. Robinson testified that she would not have agreed to the surgery if she had received such a warning. Dkt. 143, Ex. R at 137, 139.

The evidence presented is sufficient to raise an issue of material fact that the warning to the physician regarding permanent pain and nerve damage was inadequate, which means there is a question of material fact as to whether the learned intermediary doctrine bars the negligent misrepresentation claim. Ethicon's motion for summary judgment on the negligent misrepresentation claim based on the argument that it is barred by the learned intermediary doctrine is DENIED.

C. Duplicative Claims

Ethicon argues that all of Robinson's negligence-based claims are based on the same series of facts as her strict liability claims and that they fail for the same reasons her design defect and manufacturing strict liability claims fail. Dkt. 128 (citing *Gerber v. Hoffman-La Roche Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005)).

Robinson contends that summary judgment is inappropriate for the negligence claim that is based on the design defect claim and that it likewise should be denied for the gross negligence claim to the extent it derives from the design defect claim. Dkt. 143. Additionally, she contends that Ethicon has offered no evidence to support summary judgment with regard to her negligence and strict liability claims or failure to warn and that the gross negligence claim stemming from that claim should therefore survive. *Id.*

Since the court is granting summary judgment in Ethicon's favor on all of the bases for Robinson's design defect claim, the negligence and gross negligence claims based on the same facts are precluded. Ethicon's motion for summary judgment on the negligence and gross negligence claims that are based on the same facts as the dismissed design defect claims is GRANTED. To the extent these claims are based on Robinson's failure to warn claim, the motion for summary judgment is DENIED.

V. CONCLUSION

Robinson's claims for strict liability manufacturing defect (Count II), common law fraud (Count VI), fraudulent concealment as a separate cause of action (Count VII), constructive fraud (Count VIII), negligent infliction of emotional distress (Count X), breach of warranty (Counts XI and XII), violations of the Texas Deceptive Trade Practices Act (Count XIII), and unjust enrichment (Count XV), and negligence-manufacturing defect and defective product (Count IV) are DISMISSED because Robinson voluntarily withdrew these claims. Ethicon's motion for summary judgment on these withdrawn claims is DENIED AS MOOT.

Ethicon's motion for partial summary judgment (Dkt. 128) is as to Robinson's other claims is GRANTED IN PART AND DENIED IN PART. It is GRANTED with respect to Robinson's design defect claim. It is also GRANTED with respect to her negligence and gross negligence claims that are based on the design defect claim. The design defect claim and the negligence and gross negligence claims based on design defect are DISMISSED WITH PREJUDICE. The motion is DENIED with respect to Robinson's negligence and gross negligence claims to the extent those claims are based on failure to warn.

Signed at Houston, Texas on November 1, 2021.

Gray H. Miller
Senior United States District Judge